

DOE
TEC WORKING GROUP
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**Plenary I – Best Practices in
Radioactive/Hazardous Materials
Transportation**

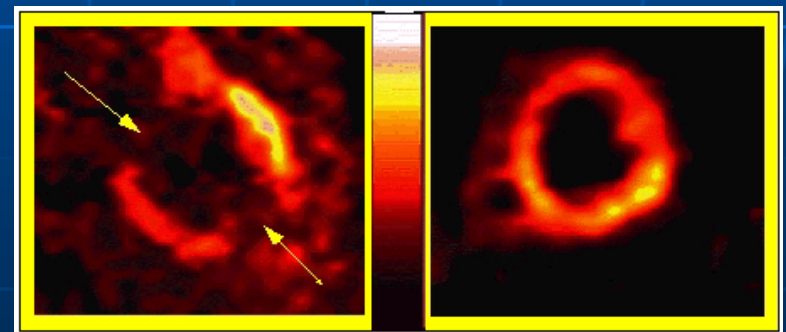
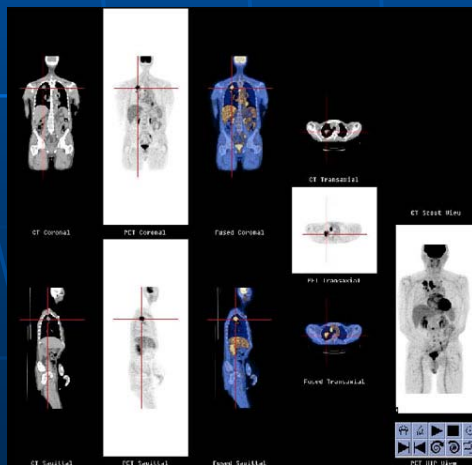
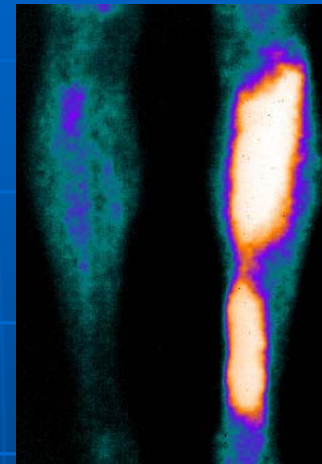
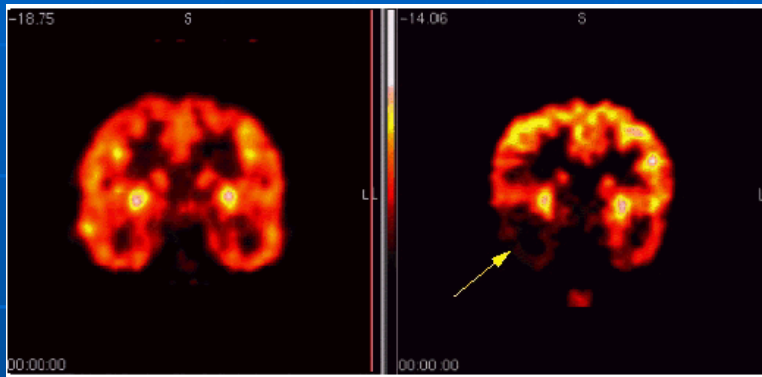
**Planning and Communications in
the Radiopharmaceutical Industry**

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Radiopharmaceuticals in Use Everyday

- 60,000 diagnostic studies performed each day in U.S.
- Used to detect cancer, heart disease, complications from AIDS
- Therapeutic radiopharmaceuticals used to relieve pain with cancer
- Therapeutic radiopharmaceuticals used to treat cancer

Radiopharmaceuticals Provide Important Medical Information



Transportation Accidents Are Rare

- More than 17 million shipments of radiopharmaceuticals are made each year in the U.S
- The accident rate is extremely low
- There is a very good history of containment of radioactive materials during accidents
- Mutual Aid between manufacturers has been extremely effective

Short Half-life Radionuclides

■ Diagnostic Imaging Radionuclides

- **Short half-lives**

- **Tc-99m** **6 hours**

- **Tl-201** **73 hours**

■ Positron Emission Tomography (PET)

- **Very short half-lives**

- **F-18** **110 min**

- **Rb-82** **1.23 min**

- **N-13** **10 min**

Radiopharmaceuticals Face New Challenges with Enhanced Security Measures

- All radiopharmaceuticals have short half-lives
- Any delays in transportation can lead to significant decay
- Enhanced security measures must be employed that do not slow transport
- Industry is busy implementing new requirements

DOT Rulemaking Requiring Transportation Security Plan

- New rule published in *Federal Register* on March 25, 2003
- Requires *Transport Security Plan* for *Highway Route Controlled Quantities* and YIII RAM shipments
- Plans must be in place by Sept 25th

Requirements of TSP

- Required for both shipper and carrier
- Must first complete *Risk Assessment*
- Risk Assessment must contain the following key elements:
 - Personnel Security
 - Unauthorized Access
 - En route Security
- Includes a training component

IAEA Plans for Enhanced Security

- IAEA has draft guidance for enhanced security
- It is more stringent than DOT's TSP requirements
- Has not been officially distributed to Competent Authorities yet

Best Practices Set Up in Radiopharmaceutical Industry

- Cooperation Between Manufacturers
 - Sharing of Safety Data
 - Sharing of Quality Data
 - Cooperation on Radiological Safety Issues
- Trade Associations Created to Deal with Regulatory/Technical Issues
 - Council on Radionuclides & Radiopharmaceuticals (CORAR)
 - Radiopharmaceutical Shippers & Carriers Conference (RSCC)

Best Practices Set Up in Radiopharmaceutical Industry Cont'd

- Participation In Rulemaking & Legislative Process
 - NRC/DOT/FDA/IAEA Rulemaking
 - Monitoring Federal & State Legislation
 - Participation in Advisory Committees
- Mutual Aid on Technical Issues
 - Transportation Incidents
 - Radiation Safety Incidents

Best Practices Set Up in Radiopharmaceutical Industry Cont'd

- Radiopharmaceutical Industry Participation in Other Groups
 - Nuclear Energy Institute
 - Society of Nuclear Medicine
 - Conference of Radiation Control Program Directors

Summary

- Radiopharmaceuticals serve important medical role
- Short half-lives require on-time transportation
- Planning and Communication is critical to assure safe, on-time deliveries
- Best Practices have improved many aspects of transportation